Remarks

Applicant appreciates the examination of the present application as evidenced by the final Office Action dated September 17, 2009 (hereinafter, the "Final Action") and the Advisory Action dated December 1, 2009 (hereinafter, the "Advisory Action"). Additionally, Applicant is appreciative of the Examiner's willingness to participate in a telephone interview to discuss the present application, which telephone interview is discussed further below.

Applicant again recognizes with appreciation the withdrawal of the rejections under 35 U.S.C. § 102(b) in view of WO 98/44350 to Blau et al.; 35 U.S.C. § 102(e) in view of U.S. Patent Application Publication No. 20030091975 to Leyland-Jones et al.; 35 U.S.C. § 102(b) in view of U.S. Patent No. 4,521,521 to Abbott et al.; 35 U.S.C. § 102(e) in view of U.S. Patent Application Publication No. 20040137425 to Upmeier et al.; and 35 U.S.C. § 102(b) in view of U.S. Patent Application Publication No. 20020107640 to Ideker et al.

Claims 30-52, 54 and 57 are pending in the present application. Applicant respectfully submits that these claims are patentable for at least the reasons below, which were conveyed during the telephone interview with the Examiner. Applicant further respectfully requests reconsideration of applicable withdrawn claims.

I. Interview Summary

During the telephone interview on December 15, 2009, the Examiner, Applicant's legal representative Dr. Shawna Cannon Lemon, inventor Professor John Colyer and Applicant's representative Lisa Brown, Ph.D., discussed U.S. Patent No. 5,798,448 to Caras et al. (hereinafter, "Caras et al.") and the present application. As summarized in the Interview Summary dated December 17, 2009, Applicant distinguished Caras et al. from the embodiments of the present invention noting, in particular, that the scaffold material of Caras et al. interacts with several binding partners in contrast to embodiments of the present invention where the scaffold material is non-reactive to any binding partner specific to the target moiety.

The present Amendment is submitted to present claim amendments and further remarks consistent with those discussed during the telephone interview in order to reduce the outstanding issues, and it is Applicant's belief, to place the application in condition for allowance.

II. Claim Rejection Under 35 U.S.C. § 102

The rejection of claim 57 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,798,448 to Caras et al. is maintained in the Final Action (*see* page 3) and Advisory Action (*see* page 2).

Applicant's arguments previously of record are relied upon herein in support of Applicant's assertion that claim 57 is not anticipated by Caras et al. Applicant provides additional remarks below that clarify the novelty of the present invention as recited in claim 57.

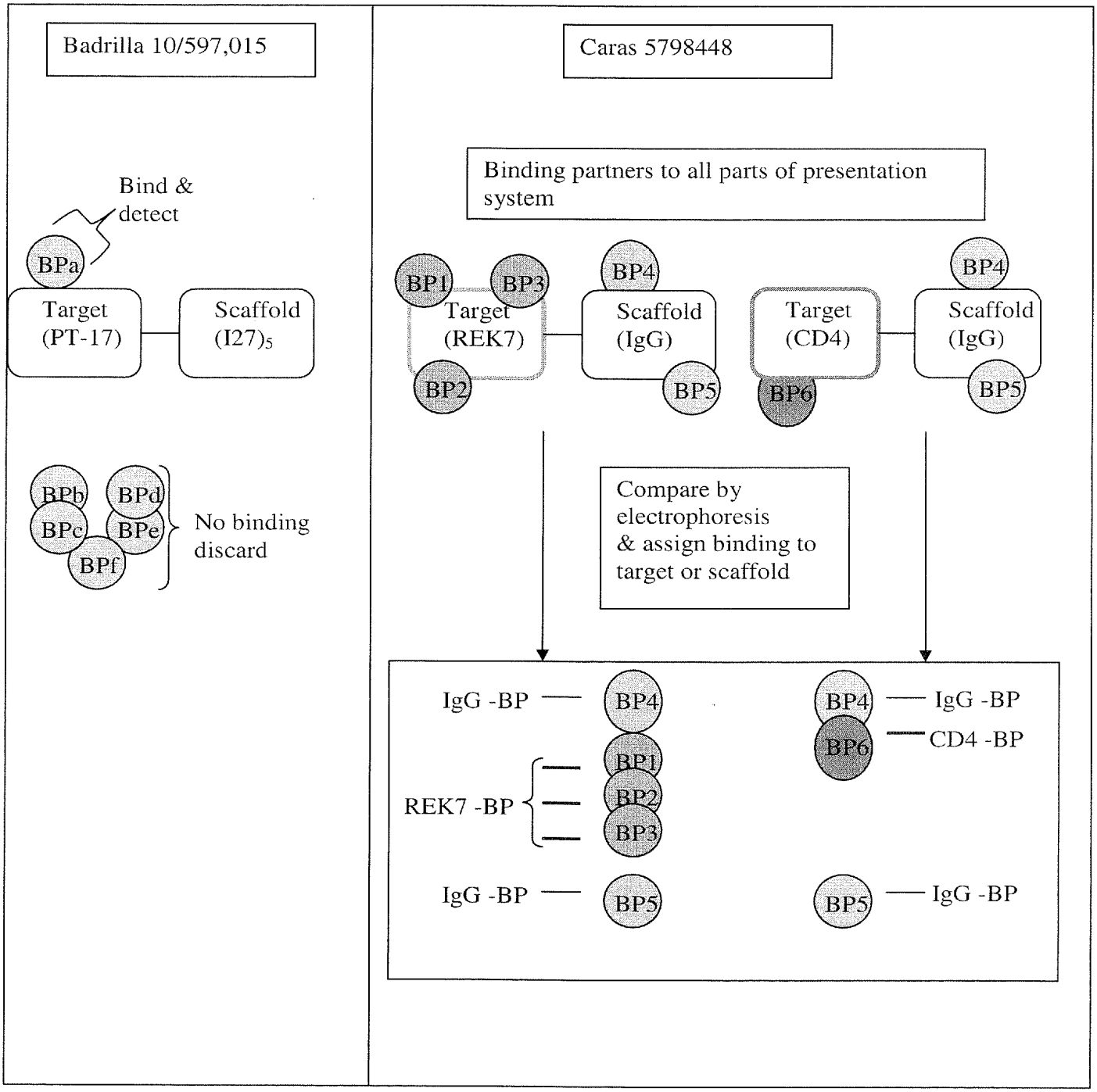
A point of novelty of the present invention over the cited reference, particularly in the content of example 5, is that the scaffold material recited in claim 57 does not interact with any detectable binding partner as can be ascertained from any of the examples shown in the present application, and this observation is most clearly illustrated in example 4. In contrast, the equivalent scaffold material of Caras et al. (i.e., the IgG domain) interacts with several binding partners. To carry out the technology described in Caras et al., one must compare the repertoire of binding partners (and not a specific binding partner as recited in claim 57) interacting with two related "presentation systems", namely REK-7:IgG and CD4:IgG in an effort to identify the binding partners which may interact with the IgG domain and other binding partners which interact with the target moiety, REK7. This comparison is relevant for one utilizing the Caras et al. technology to identify binding partners of the target moiety, whereas it is **not** required, relevant or used to identify binding partners of the target moiety in embodiments of the present invention, as no detectable binding partners are capable of interacting with the scaffold material recited in the pending claims.

Turning to example 4 of the present application, example 4 describes an example in which three different target moieties (molecules A1, PS-38 and PT-17) were covalently attached to two different scaffold molecules ($(I27)_5$ and I39-$(I27)_4$) creating six different presentation systems. Two further materials of the scaffold materials alone ($(I27)_5$ and I39-$(I27)_4$) were also prepared. A series of similar and dissimilar biological specimens were exposed to these presentation systems in an effort to identify binding partners in the biological samples to each of the three target moieties. Two of the biological specimens were rabbit serum samples, which contain large numbers of different binding partners in the form of antibody molecules (Immunoglobulin G class antibodies). While the raw data were not

included in the present application, the results were described – namely each rabbit serum sample contained binding partners which bound to only one target moiety specifically and failed to interact with presentation systems displaying alternatives and failed to interact with the scaffold materials alone. For the Examiner's reference and merely to supplement the previously provided description of the results, the raw data are provided as Figure A submitted herewith.

The structure of this experiment is similar to that of Caras et al., in that a biological specimen is being exposed to relevant and irrelevant target moieties within their respective presentation system. The outcome is however importantly different. In the present application, none of the biological specimens contain detectable binding partners of the scaffold material, whereas in the Caras et al. experiment, the biological specimen does contain binding partners to the target moiety and to the scaffold material. It is a relevant feature of the embodiments of the present invention that the scaffold material is not recognized by any detectable specific binding partner, so that target moiety binding partners can be identified unambiguously using a single presentation system material alone.

This result would not be achievable with the technology of Caras et al. as in Caras et al., binding partners to both parts of the presentation system (target and scaffold) are detected and require comparison with additional "control experiment" information to be able to assign binding partners to the target moiety and scaffold material, respectively. To assist the Examiner's understanding, this distinction is illustrated below in a schematic representation of embodiments of the present invention and the technology presented in Caras et al.



In Caras et al., Applicant respectfully submits that a number of detectable binding partners (BP) bind to "target" and "scaffold" regions of the presentation system. A comparison of different presentation systems comprising common "scaffold" regions but

different "target" regions is necessary and essential to identify which binding partners (BP) bind to which component of the presentation system. This is performed by SDS-PAGE, which separates components according to their molecular weight. Protein binding partners of identical size eluting from the REK7-IgG and CD4-IgG presentation system (e.g. BP4 and BP5 in the schematic) are assigned as scaffold (IgG) binding partners as this material is common to both presentation systems. Proteins BP1-3 are unique to the REK7-IgG presentation system and therefore are likely to be REK7 binding partners. BP6 is unique to the CD4-IgG presentation system and is therefore likely to be a CD4 binding partner. Regarding embodiments of the present invention, as can be ascertained from the present application, no detectable binding partners (BP) bind to the "scaffold" region of the presentation system. Binding partners of the "target" region are readily identified. There is no need for comparison between different presentation systems.

Applicant has amended claim 57 in order to clarify further the distinction between the presently claimed invention and the technology described in Caras et al. as shown below:

> 57. A non-natural presentation system, comprising at least one copy of a target moiety or part thereof that is recognizable by a binding partner and at least one domain of a scaffold material covalently linked to said target moiety wherein the scaffold material has a controllable property selected from the group consisting of:
> (i) molecular weight;
> (ii) isoelectric point;
> (iii) number of chemically reactive cysteine amino acid residues; and
> (iv) number of chemically reactive lysine amino acid residues,
> wherein the at least one domain of the scaffold is ***non-reactive*** to any ***detectable*** binding partner of the presentation system.

At least in view of the foregoing, it is apparent that Caras et al. does not anticipate the presently claimed invention. There is clearly a difference between the claimed invention and the disclosure of Caras et al. as viewed by one of ordinary skill in the art, and the technology described in Caras et al. fails to adequately describe the claimed invention so that a person of ordinary skill in the art could make and use the invention. Therefore, Applicant respectfully requests that the rejection of claim 57 under 35 U.S.C. §102(b) in view of Caras et al. be withdrawn.

II. Claim Rejection Under 35 U.S.C. §103

The rejection of claim 30 under 35 U.S.C. § 103(a) as being obvious in view of Caras et al. in view of U.S. Patent No. 4,208,479 to Zuk et al. (hereinafter, "Zuk et al.") is maintained in the Final Action (*see* page 3) and Advisory Action in general.

For reasons discussed above, Caras et al. does not teach the presently claimed invention. Zuk et al. does not cure the deficiencies of Caras et al. More specifically, as noted previously, Zuk et al. describes an immunoassay capable of calibrating to measure antigen-antibody or ligand-antiligand components quantitatively. The assay relies upon competition between a labelled ligand and the corresponding unlabelled ligand for access to an anti-ligand. At most, Zuk et al. describes the composition of a kit to execute their technology.

Both Caras et al. and Zuk et al. differ markedly from the presently claimed invention and provide no teaching or direction to one of ordinary skill in the art toward the presently claimed invention. These references fail to render the present invention obvious either alone or in combination, and Applicant respectfully requests that this rejection of claim 30 under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicant respectfully submits that the present application is in condition for allowance and the same is earnestly solicited. The Examiner is encouraged to telephone the undersigned at 919-854-1400 for resolution of any outstanding issues.

Respectfully submitted,

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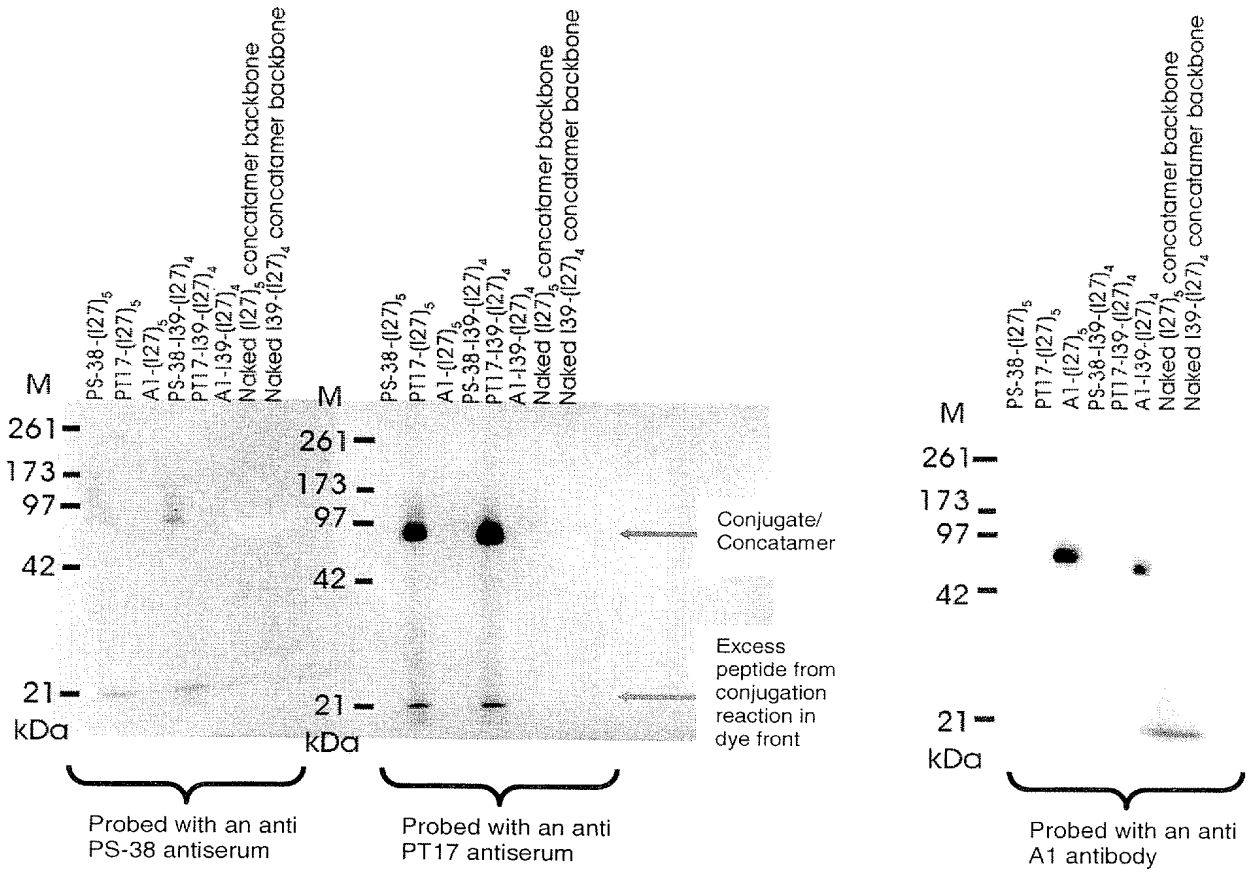

Figure A: Three biological specimens contain binding partners specific for individual target moieties and contain no binding partners to the scaffold materials. Techniques for conjugation and western blot are described in the present application U.S. Patent Application Serial No. 10/597,015. A rabbit polyclonal antiserum PS-38 contains binding partners that recognize target moiety PS-38, and do not recognize either the scaffold material (labelled Naked (I27)5 concatamer backbone, Naked I39(I27)4 concatamer backbone) or other target moieties. An identical pattern is seen with a second biological specimen including a rabbit polyclonal antiserum PT-17 that recognize target moiety PT-17 and nothing else (neither scaffold molecules nor irrelevant target moieties). An identical pattern is seen with a third biological specimen including a mouse monoclonal antibody A1 that recognizes target moiety A1 and nothing else (neither scaffold molecules nor irrelevant target moieties).